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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/631,863	08/03/2000	Renate Konopitzky	12/211	8920

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EXAMINER

DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 05/22/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/631,863

Applicant(s)

KONOPITZKY ET AL.

Examiner

MINH-TAM DAVIS

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-58 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, 17, 33-34, drawn to a tumor associated antigen of SEQ ID NO:2, fragments thereof of SEQ ID Nos: 88-102, classified in class 530, subclass 350.
- II. Claims 6-8, 36, drawn to a tumor associated antigen of SEQ ID NO:2, fragments thereof of SEQ ID Nos: 88-102, which are presented by an MHC molecule, or at least two different HLA molecules, classified in class 530, subclass 350.
- III. Claim 9, drawn to a derivative of a tumor associated antigen of SEQ ID NO:2, classified in class 530, subclass 350.
- IV. Claims 10-11, 14-16, drawn to a method for treating cancer comprising administering SEQ ID NO:2 or fragments thereof, classified in class 514, subclass 2.
- V. Claims 10-11, 14-16, drawn to a method for preventing cancer comprising administering SEQ ID NO:2 or fragments thereof, classified in class 514, subclass 2.
- VI. Claims 12-13, 14-16, drawn to a method for treating cancer comprising administering CTLs specific for SEQ ID NO:2 or fragments thereof, classified in class 424, subclass 93.7.

- VII. Claims 12-13, 14-16, drawn to a method for preventing cancer comprising administering CTLs specific for SEQ ID NO:2 or fragments thereof, classified in class 424 subclass 93.7.
- VIII. Claims 18-21, 33-34, drawn to a tumor associated antigen of SEQ ID NO:3 , fragments thereof of SEQ ID Nos: 44-87, classified in class 530, subclass 350.
- IX. Claims 22-24, 36, drawn a tumor associated antigen of SEQ ID NO:3 , fragments thereof of SEQ ID Nos: 44-87, which are presented by an MHC molecule, or at least two different HLA molecules, classified in class 530, subclass 350.
- X. Claim 25, drawn to a derivative of a tumor associated antigen of SEQ ID NO:3, classified in class 530, subclass 350.
- XI. Claims 26-27, 30-32, drawn to a method for treating cancer comprising administering SEQ ID NO:3 or fragments thereof, classified in class 514, subclass 2.
- XII. Claims 26-27, 30-32, drawn to a method for preventing cancer comprising administering SEQ ID NO:3 or fragments thereof, classified in class 514, subclass 2.
- XIII. Claims 28-29, 30-32, drawn to a method for treating cancer comprising administering CTLs specific for SEQ ID NO:3 or fragments thereof, classified in class 424, subclass 93.7.

- XIV. Claims 28-29, 30-32, drawn to a method for preventing cancer comprising administering CTLs specific for SEQ ID NO:3 or fragments thereof, classified in class 424, subclass 93.7.
- XV. Claim 35, drawn to one or more fragments of SEQ ID Nos: 88-102, and one or more fragments from a tumor-associated antigen which is not R11, classified in class 530, subclass 300.
- XVI. Claim 37, drawn to one or more fragments of SEQ ID Nos: 88-102, and one or more fragments from a tumor-associated antigen which is not R11, which are presented by at least two MHC molecules, classified in class 530, subclass 300.
- XVII. Claims 35, drawn to one or more fragments of SEQ ID Nos: 44-87, and one or more fragments from a tumor-associated antigen which is not R11, classified in class 530, subclass 300.
- XVIII. Claims 37, drawn to one or more fragments of SEQ ID Nos: 44-87, and one or more fragments from a tumor-associated antigen which is not R11, which are presented by at least two MHC molecules, classified in class 530, subclass 300.
- XIX. Claims 38-40, 43-45, 47, drawn to a nucleotide sequence encoding SEQ ID NO:2, or fragments thereof, classified in class 536, subclass 23.1.
- XX. Claims 39-40, 43-45, 47, drawn to a nucleotide sequence encoding SEQ ID NO:3, or fragments thereof, classified in class 536, subclass 23.1.

- XXI. Claims 40-42, drawn to a nucleotide sequence of SEQ ID NO:1, classified in class 536, subclass 23.1.
- XXII. Claim 46, drawn to a method for treating cancer comprising administering a nucleic acid sequence encoding SEQ ID NO:2 or fragments thereof, classified in class 514, subclass 44.
- XXIII. Claim 46, drawn to a method for treating cancer comprising administering a nucleic acid sequence encoding SEQ ID NO:3 or fragments thereof, classified in class 514, subclass 44.
- XXIV. Claim 46, drawn to a method for treating cancer comprising administering a nucleic acid sequence of SEQ ID NO:1 or fragments thereof, classified in class 514, subclass 44.
- XXV. Claim 46, drawn to a method for preventing cancer comprising administering a nucleic acid sequence encoding SEQ ID NO:2 or fragments thereof, classified in class 514, subclass 44.
- XXVI. Claim 46, drawn to a method for preventing cancer comprising administering a nucleic acid sequence encoding SEQ ID NO:3 or fragments thereof, classified in class 514, subclass 44.
- XXVII. Claim 46, drawn to a method for preventing cancer comprising administering a nucleic acid sequence of SEQ ID NO:1 or fragments thereof, classified in class 514, subclass 44.
- XXVIII. Claims 48-51, drawn to an antibody specific for SEQ ID NO:2 or fragments thereof, classified in class 530, subclass 387.1.

- XXIX. Claims 48-51, drawn to an antibody specific for SEQ ID NO:3 or fragments thereof, classified in class 530, subclass 387.1.
- XXX. Claims 52-53, drawn to a method for treating cancer, comprising administering an antibody specific for SEQ ID NO:2 or fragments thereof, classified in class 424, subclass 130.1.
- XXXI. Claims 52-53, drawn to a method for treating cancer, comprising administering an antibody specific for SEQ ID NO:3 or fragments thereof, classified in class 424, subclass 130.1.
- XXXII. Claims 52-53, drawn to a method for preventing cancer, comprising administering an antibody specific for SEQ ID NO:2 or fragments thereof, classified in class 424, subclass 130.1.
- XXXIII. Claims 52-53, drawn to a method for preventing cancer, comprising administering an antibody specific for SEQ ID NO:3 or fragments thereof, classified in class 424, subclass 130.1.
- XXXIV. Claims 54-56, drawn to a method for diagnosing or screening cancer, using an antibody specific for SEQ ID NO:2 or fragments thereof, classified in class 435, subclass 7.1
- XXXV. Claims 54-56, drawn to a method for diagnosing or screening cancer, using an antibody specific for SEQ ID NO:3 or fragments thereof, classified in class 435, subclass 7.1

XXXVI. Claims 54-55, 57, drawn to a method for diagnosing or screening cancer, using a labeled polypeptide comprising SEQ ID NO:2 or fragments thereof, classified in class 435, subclass 7.1

XXXVII. Claims 54-55, 57, drawn to a method for diagnosing or screening cancer, using a labeled polypeptide comprising SEQ ID NO:3 or fragments thereof, classified in class 435, subclass 7.1

XXXVIII. Claims 54-55, drawn to a method for diagnosing or screening cancer, comprising detecting an increase in the level of a nucleic acid encoding SEQ ID NO:2, classified in class 435, subclass 6.

XXXIX. Claims 54-55, drawn to a method for diagnosing or screening cancer, comprising detecting an increase in the level of a nucleic acid encoding SEQ ID NO:3, classified in class 435, subclass 6.

XXXX. Claim 58, drawn to a kit comprising SEQ ID NO:2 or fragments or derivative thereof, and an antibody specific for SEQ ID NO:2 or fragments or derivative thereof, classified in class 530, subclasses 350 and 387.1.

XXXXI. Claim 58, drawn to a kit comprising SEQ ID NO:3 or fragments or derivative thereof, and an antibody specific for SEQ ID NO:3 or fragments or derivative thereof, classified in class 530, subclasses 350 and 387.1.

In addition, upon election of any of groups I, IV, V, VIII, XI-XII, XIX-XX, XXII-XXVI, XXVII-XXXVII, XXXX-XXXXI, further election of the following species is required:

Full length sequence or fragments thereof..

Upon election of the species fragments, further election of a single fragment is required.

Upon election of any of groups XV-XVIII further election of the following species is required:

A single combination of one or more fragments of SEQ ID NO:2 or SEQ ID NO:3 and one or more fragments of a tumor associated antigen which is different from R11.

Upon election of any of groups IV-VII, XI-XIV, XXII-XXVII, XXX-XXXIX further election of the following species is required:

Any one of the cancers recited in claim 15, or claim 31.

Upon election of any of groups IV-VII, XI-XIV further election of the following species is required:

Route of administration, which is parenterally, topically, orally or locally.

The inventions are distinct, each from each other because of the following reasons:

Inventions (I, VI, XI-XV, XXII-XXIII, XXXIV-XXXV) and (II-V, VII-X, XVI-XXI, XXIV-XXXIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05 (h)). In this instant case, a polypeptide could be used for several purposes, e.g. for biochemical assay, for making antibodies, and for making an affinity column to purify its antibodies; a DNA sequence could be used for the detection of

similar DNA or RNA sequences, for making an expression vector, and for producing its encoded protein; and an antibody could be used for immunoassay, for purification of its antigen, and for detection of diseases.

The products of groups I, VI, XI-XV, XXII-XXIII, XXXIV-XXXV are patentably distinct, because they are drawn to entirely different biochemicals, having different structures, biological properties and activities that are not interchangeable and cannot be used in place of each other.

The methods of groups II-V, VII-X, XVI-XXI, XXIV-XXXIII are distinct from each other because they differ at least in objectives, method steps, reagents and/or dosages, and/or schedules used, response variables and criteria for success.

The species full length sequence, or fragments or derivatives are distinct because they are structurally distinct.

The species cancer are distinct, because they are different diseases with different etiology.

The species route of administration are distinct from each other because they differ at least in method steps, schedules used, response variables and criteria for success.

Because these inventions are distinct for the reason given above and have acquired a separate status in the art, and because the searches for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted. Applicant is further

advised that if Applicant elects a group having species requirement, a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

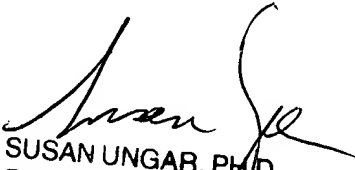
Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

MINH TAM DAVIS

May 21, 2002


SUSAN UNGAR, PHD
PRIMARY EXAMINER

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